

AMENDMENTS TO THE DRAWINGS

Attached are three (3) sheets of replacement formal drawings depicting Figures 1-8b for the originally filed Figures 1-8b.

Attachment: Replacement Sheets (3)

REMARKS/ARGUMENTS

Claims 1-30 are pending. The specification and claims have been amended and formal versions of Figures 1-8 are provided.

Prompt and favorable consideration are earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



Paul T. Bowen
Reg. No. 38,009

PTB:jck

Attachments:

Abstract

Replacement Figures 1-8 (3 sheets)

Marked-up Specification

Clean Specification

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

10/563857

**Respiratory Mask Arrangement As Well As Headband Arrangement And
Respiratory Gas Evacuation Device For A Respiratory Mask**

IAP20 Res 4 PCT/PTO 09 JAN 2006

5 **Specification**

CROSS REFERENCE TO PRIORITY APPLICATION

10 This application is a national phase application of PCT/EP2004/007599, filed July 9, 2004, which claims the benefit of German Application No. 103 31 134.3, filed July 9, 2003 and German Application No. 103 35 162.0, filed July 30, 2003, pending, each incorporated herein by reference in its entirety.

Field of the Invention

15 The invention relates to a respiratory mask arrangement, of the kind that can be used for instance in CPAP therapy for the treatment of sleep-related breathing disorders. The invention also relates to a headband arrangement for a respiratory mask and to a respiratory gas evacuation device for a respiratory mask arrangement, for evacuating CO₂-laden respiratory mask.

20

Background of the Invention

25 In the aforementioned CPAP therapy, a breathable gas, in particular ambient air, can be delivered to a patient via a respiratory mask at a pressure level that is above the ambient pressure level. By means of the respiratory gas that is under pressure, a pneumatic tracking of the upper airways can be attained, and any obstructions can thereby be averted. In carrying out a pressurized breathing or CPAP therapy, the respiratory mask arrangements required for delivering the respiratory gas are typically worn by the patient for the entire duration of the patient's sleeping or resting phase. The respiratory mask
30 arrangement is typically braced via a sealing lip zone in the region surrounding the mask

user's nose and via a forehead-mounted device in the region of the mask user's forehead. The retention forces required to apply the respiratory mask arrangement may be brought to bear by a fixation device, which for example has a headband that extends around the back of the mask user's head. The evacuation of the respiratory gas, which may be laden with CO₂, from the interior region of the respiratory mask can be done via bores whose open cross section is defined such that a sufficiently great outflow of the respiratory gas is made possible.

Object of the Invention

It is the object of the invention to furnish embodiments by which a reliable evacuation of CO₂-laden respiratory gas from the interior region of a respiratory mask arrangement is advantageously assured.

Attainment of the Object According to the Invention

In a first aspect, A respiratory mask arrangement having a sealing lip device for resting on the facial surface of a mask user, a covering device which in cooperation with the sealing lip device defines a mask interior, a respiratory gas evacuation device for delivering respiratory gas to the mask interior defined by the covering device, this mask interior communicating with the nostril and/or the oral opening of the mask user; the covering device is embodied at least in some portions as a permeable structure.

It thus becomes advantageously possible to create a respiratory mask arrangement which furnishes a gas outflow area that enables a diffuse outflow of gas while emitting little noise.

The covering device is preferably made from an air-permeable woven material, in particular Gore-Tex material. As an alternative to this provision, or in combination with it, it is also possible to make the covering device from a porous material.

Especially advantageously, the covering device is made from a flexible material which is deployed in the mask interior under the influence of pressure. The air permeability of the air-permeable material and the area of the portion defined thereby are selected such that a sufficient outflow of gas from the mask interior is assured.

The covering device or the sealing lip device may be coupled with a headband arrangement. The headband arrangement itself may likewise be used to furnish a gas outflow area. This gas outflow area can be formed by a hoselike zone of an air-permeable hose material.

The sealing lip device is preferably glued or vulcanized or sprayed onto the covering device. It is also possible to couple the covering device detachably with the sealing lip device, or to embody the sealing lip device integrally with the covering device. It is possible to deploy the covering device by means of supporting wall structures.

The covering device may also have a hard shell body and a woven outlet portion coupled to the hard shell body. This woven outlet portion preferably has an area of at least 3.7 cm².

The invention also relates to a headband arrangement for a respiratory mask; the headband arrangement in at least some portions is made of an air-permeable material and includes a conduit unit which is in communication with a mask interior defined by the respiratory mask, in such a manner that an outflow from the mask interior of respiratory gas that is under pressure can be effected through the air-permeable material portion provided in the headband.

Advantageous features of this invention are the subject of the dependent claims.

The object stated initially above is also attained, in a further aspect, by a respiratory mask arrangement having an arched member, a sealing lip device for resting on the facial surface of a mask user, and a respiratory gas conduit unit for delivering respiratory gas to a mask interior that is defined by the arched member and is in communication with the nostril and/or the oral opening of the mask user; in cooperation with the arched member, an air guide path is defined that extends from a respiratory gas inlet area to a respiratory gas outlet area and extends at least in some portions along a wall defining the arched member.

As a result, it advantageously becomes possible to create a respiratory mask arrangement that is easily cleaned and is distinguished by low noise and an only slight idle volume.

~~Advantageous features of this invention are the subject of the applicable dependent claims.~~

Brief Description of the Drawings

Further details and characteristics of the invention will become apparent from the ensuing description in conjunction with the drawings. Shown are:

Fig. 1, a sketch for explaining a first embodiment of a respiratory mask according to the invention;

Fig. 2, a sketch for explaining a second embodiment of a respiratory mask;

Fig. 3, a sketch for explaining a woven material portion;

Fig. 4, a sketch for explaining the micropore structure obtained by a loose hook-and-loop fastening in a woven material;

Fig. 5, a sketch for explaining an outlet insert, formed of a woven material, for a hard shell for the mask;

Fig. 6, a sketch for explaining an embodiment of the invention for attaining the second
5 aspect of the object of the invention;

Fig. 7, a sketch for explaining a preferred construction of a hard shell and of an insert element intended to be inserted into it;

10 **Fig. 8a**, a sketch for explaining a preferred embodiment of an insert element of the application structure of the respiratory mask arrangement shown above;

Fig. 8b, a sketch for explaining a preferred internal design of a hard shell with a receiving portion for receiving the insert element of Fig. 8a.

15

Detailed Description of the Drawings

The respiratory mask arrangement shown in Fig. 1 includes a sealing lip device 1, made from an elastomer material, in particular silicone rubber, and a covering device 2. The
20 sealing lip device 1 is embodied such that it encompasses a receiving opening, intended to receive the nasal region of a mask user, and preferably crosses over the bridge of the nose and the upper lip region of the mask user. The sealing lip device 1 thus has a substantially saddle-shaped silhouette.

25 The covering device 2 is embodied such that in cooperation with the sealing lip device 1, it defines a mask interior. The mask interior is in communication with a respiratory gas conduit unit 3, for delivering respiratory gas to the mask interior defined by the covering device and communicating with the nostril and/or the oral opening of the mask user. The covering device is embodied in at least some portions as an air-permeable woven
30 structure. The respiratory gas conduit unit 3 forms a connection stub for coupling a

respiratory gas hose. The respiratory mask arrangement shown serves to deliver respiratory gas at a pressure level that is above the ambient pressure. Under the influence of the pressure, the covering device 2 is deployed in the mask interior between its peripheral attachment points, that is, between the sealing lip device 2 and the respiratory gas conduit unit 3.

Fig. 2 shows a further variant of a respiratory mask. In this mask, the covering device 2 is embodied as stitched by means of seam segments 2a, 2b, 2c, 2d. The course of the seam segments and the shape of the woven zones located between them are adapted such that the covering device is given a defined shape under the influence of the respiratory gas pressure.

It is also possible to place the covering device on a ribbed structure, or to embody it as an insert element for a hard shell.

Instead of a woven material, nonwoven or filter materials or other kinds of porous materials may be used, such as micro perforated plastic films.

Fig. 3 shows a detail of a covering device made from a woven material.

Fig. 4 shows warp threads 5 and weft threads 6 of the woven portion of Fig. 3. Between the warp and weft threads, interstices are defined through which CO₂-laden respiratory gas can escape from the mask interior.

Fig. 5 shows an insert element for a hard mask shell. The insert element includes a porous zone 7, which is made from an air-permeable material. Via this porous zone, CO₂-laden respiratory gas can escape from the mask interior.

The respiratory masks described can be secured by means of headband arrangements.

These headband arrangements can be used to evacuate respiratory gas, because they have air-permeable zones which communicate with the mask interior via a conduit unit.

- 5 The respiratory mask arrangement shown in Fig. 6 includes a sealing lip device 21, made from an elastomer material, in particular silicone rubber, and an arched member 22. The sealing lip device 21 is embodied such that it encompasses a receiving opening, intended to receive the nasal region of a mask user, and preferably crosses over the bridge of the nose and the upper lip region of the mask user. The sealing lip device 21 thus has a
10 substantially saddle-shaped silhouette.

The arched member is embodied such that it defines an air guide path 23, which extends from a respiratory gas inlet area E to a respiratory gas outlet area A, and extends at least in some portions along a wall that defines the arched member 22.

15

The air guide path 23 is defined, toward the mask interior region, by an insert element 24. The arched member 22 is also provided with a fixation device, for installing the insert element 24. A covering portion 24a is embodied on the insert element 24 and rests on a fluted conduit structure 25, which is embodied in the inner region of the sealing lip device
20 21.

As can be seen from Fig. 7, the insert element 24 can be installed in the inner region of the arched member 22. A receiving portion 26 is embodied in the inner region of the arched member 22, for receiving the insert element 24.

25

As can be seen from Fig. 8a, conduit structures 27 are embodied in the insert element 24. The conduit structures 27 are adapted such that a defined flow resistance is obtained. The conduit structures 27 extend from an inlet region E to an outlet region A. In the installed state, the conduit portions 27 are covered by the wall of the arched member 22. The insert
30 element 24 is made from an elastomer material. In the insert element 24, labyrinth

structures are formed by the conduit portions 27. The insert element 24 can be coupled to the arched member by clamping action. For additional sealing, a sealing lip 24c extending all the way around is embodied on the insert element 24. The insert element 24 shown here can be inserted from the inside into the arched member 22 shown in Fig. 8b.

5

As can be seen from Fig. 8b, there are outlet openings A1, A2 in the arched member 22, which match the outlet region A of the insert element and make an outflow of the used breathing air possible. In this exemplary embodiment, the arched member 22 itself is made of a thermoplastic material. The receiving region 32 intended for receiving the

10

insert element 24 can be defined by an indentation or by a circumferential wall.

It is also possible to accomplish the fixation of the insert element by means of pegs or other retention means.

15

The insert element is embodied here by a low rectangular body. It is also possible to design the insert element in some other way, in particular as a cylindrical disk or as a polygonal prism. The insert element can also be designed such that certain throttling effects are obtained as a result of its position on the arched member.

20

The insert element may also be designed such that as a function of the internal pressure, various flow resistances are obtained, in particular by deformation of the conduit portions 27.

Claims

1. A respiratory mask arrangement having a sealing lip device for resting on the facial
5 surface of a mask user, a covering device which in cooperation with the sealing lip device defines a mask interior, a respiratory gas evacuation device for delivering respiratory gas to the mask interior defined by the covering device, this mask interior communicating with the nostril and/or the oral opening of the mask user, wherein the covering device is embodied at least in some portions as a permeable structure.
- 10 2. The respiratory mask arrangement in accordance with claim 1, characterized in that the covering device is made from an air-permeable woven material, in particular Gore-Tex material.
- 15 3. The respiratory mask arrangement in accordance with claim 1, characterized in that the covering device is made from a porous material.
4. The respiratory mask arrangement in accordance with at least one of claims 1-3, characterized in that the covering device is made from a flexible material which is
20 deployed in the mask interior under the influence of pressure.
5. The respiratory mask arrangement in accordance with at least one of claims 1-4, characterized in that the air permeability of the air-permeable material and the area of the portion defined thereby are selected such that a sufficient outflow of gas from the
25 mask interior is assured.
6. The respiratory mask arrangement in accordance with at least one of claims 1-5, characterized in that the covering device is coupled with a headband arrangement.

7. The respiratory mask arrangement in accordance with at least one of claims 1-6, characterized in that the headband arrangement is likewise used to furnish a gas outflow area.
- 5 8. The respiratory mask arrangement in accordance with at least one of claims 1-7, characterized in that the sealing lip device is glued or vulcanized or sprayed onto the covering device.
- 10 9. The respiratory mask arrangement in accordance with at least one of claims 1-7, characterized in that the covering device is detachably coupled with the sealing lip device.
- 15 10. The respiratory mask arrangement in accordance with at least one of claims 1-9, characterized in that the sealing lip device is embodied integrally with the covering device.
- 20 11. The respiratory mask arrangement in accordance with at least one of claims 1-10, characterized in that supporting wall structures are provided, for deploying the covering device.
- 25 12. The respiratory mask arrangement in accordance with at least one of claims 1-11, characterized in that the supporting wall structures form part of a skeletal structure.
13. The respiratory mask arrangement in accordance with at least one of claims 1-12, characterized in that the covering device has a hard shell body and a woven outlet portion coupled to the hard shell body.
14. The respiratory mask arrangement in accordance with claim 13, characterized in that the woven outlet portion has an area of at least 3.7 cm².

15. A headband arrangement for a respiratory mask, wherein the headband arrangement in at least some portions is made of an air-permeable material and includes a conduit unit which is in communication with a mask interior defined by the respiratory mask, in such a manner that an outflow from the mask interior of respiratory gas that is under
5 pressure can be effected through the air-permeable material portion provided in the headband.

16. A respiratory mask arrangement having an arched member, a sealing lip device for resting on the facial surface of a mask user, and a respiratory gas line unit for
10 delivering respiratory gas to a mask interior that is defined by the arched member and is in communication with the nostril and/or the oral opening of the mask user, wherein in cooperation with the arched member, an air guide path is defined that extends from a respiratory gas inlet area to a respiratory gas outlet area and extends at least in some portions along a wall delimiting the arched member.

15 17. The respiratory mask arrangement in accordance with claim 16, characterized in that the air guide path is delimited by an insert element.

18. The respiratory mask arrangement in accordance with claim 17, characterized in that
20 the arched member is provided with a fixation device, for installing the insert element.

19. The respiratory mask arrangement in accordance with at least one of claims 16-18, characterized in that the insert element can be installed in the inner region of the arched member.

25 20. The respiratory mask arrangement in accordance with at least one of claims 16-19, characterized in that a receiving portion, for receiving the insert element, is embodied in the inner region of the arched member.

21. The respiratory mask arrangement in accordance with at least one of claims 16-20, characterized in that conduit structures are embodied in the insert element.

22. The respiratory mask arrangement in accordance with at least one of claims 16-21,
5 characterized in that the conduit structures are adapted such that a defined flow resistance is obtained.

23. The respiratory mask arrangement in accordance with at least one of claims 16-22,
10 characterized in that the conduit portions are covered by the walls of the arched member.

24. The respiratory mask arrangement in accordance with at least one of claims 16-23, characterized in that the arched member is made from an elastomer material.

15 25. The respiratory mask arrangement in accordance with at least one of claims 16-24, characterized in that the arched member is embodied integrally with the sealing lip device.

26. The respiratory mask arrangement in accordance with at least one of claims 16-25,
20 characterized in that the arched member is provided with openings for evacuating CO₂-laden respiratory gas.

27. The respiratory mask arrangement in accordance with at least one of claims 16-26,
25 characterized in that the insert element is made from an elastomer material.

28. The respiratory mask arrangement in accordance with at least one of claims 16-27, characterized in that labyrinth structures are embodied in the insert element.

29. The respiratory mask arrangement in accordance with at least one of claims 16-28, characterized in that the insert element is coupled to the arched member by clamping action.
- 5 30. An insert element for a respiratory mask arrangement in accordance with at least one of claims 16-29.